

K090677

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510(k) SUMMARY

**510(K) NUMBER:** K090677  
**SUBMITTED BY:** Innovia LLC  
12415 SW 136 Avenue  
Unit 3  
Miami, FL 33186  
305-378-2651  
**CONTACT PERSON:** Bruce Weber  
Vice President, Clinical, Regulatory and Quality Assurance  
**DATE OF PREPARATION:** May 6, 2009  
**NAME OF DEVICE:** Laparoscopic Access Port  
**CLASSIFICATION:** Laparoscope, General & Plastic Surgery (21CFR 876.1500)  
**TRADE NAME:** InnoPort™ Laparoscopic Access Port  
**PREDICATE DEVICE:** Advanced Surgical Concepts TriPort Laparoscopic Access Device (K073719)  
Ethicon Endopath Blunt Tip Trocar (K032676)

**INTENDED USE:** The InnoPort™ Laparoscopic Access Port is a sterile, single use device, intended for use as a multiple instrument and/or camera port during minimally invasive laparoscopic abdominal surgery.

**DEVICE DESCRIPTION:** The InnoPort™ Laparoscopic Access Port is a sterile, single use laparoscopic access device made of a flexible Quatromer polymer combined with polycarbonate and polyurethane components. It forms a truncated cone approximately 5.0 centimeters long (not including instrument ports), with three individual laparoscopic instrument ports at the larger end. A fourth port connects to the insufflation system to provide intra-abdominal pneumoperitoneum. The instrument ports are designed to accommodate 5 mm diameter laparoscopic instruments while allowing full maneuverability without loss of pneumoperitoneum. The complete device is designed to be inserted through a single incision into the abdominal cavity for the duration of surgery.

**PERFORMANCE DATA SUMMARY:** The performance and functional testing of the InnoPort™ Laparoscopic Access Port included bench and *in vivo* tests to verify its ability to maintain pneumoperitoneum with minimal leakage, allow introduction and manipulation of instruments, and meet performance specifications. The testing demonstrated that the InnoPort™ Laparoscopic Access Port is substantially equivalent to its predicate device and it introduces no new safety or effectiveness issues when used as instructed.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY - 7 2009

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Innovia LLC  
% Mr. Bruce Weber  
VP, Clinical, Regulatory and QA  
12415 SW 136 Avenue, Unit 3  
Miami, Florida 33186

Re: K090677

Trade/Device Name: Innovia InnoPort™ Laparoscopic Access Port  
Regulation Number: 21 CFR 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: II  
Product Code: GCI  
Dated: June 30, 2009  
Received: June 30, 2009

Dear Mr. Weber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

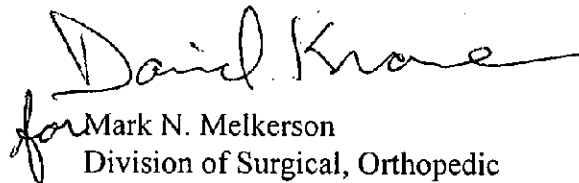
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Mr. Bruce Weber

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink that reads "David Krone". The signature is fluid and cursive, with a long horizontal stroke at the end.

for Mark N. Melkerson  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K090677

## Indications for Use

510(k) Number: K090677

Device Name: Innovia InnoPort™ Laparoscopic Access Port

### Indications for Use:

The Innovia InnoPort™ Laparoscopic Access Device is a sterile, single use device intended for use as a multiple instrument and/or camera port during minimally invasive laparoscopic abdominal surgery.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nail R. Dyden, Foreman  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

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